

REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. CLAIM STATUS

Claims 27-44, 48-50 and 52 are pending in this application.

Claims 31-34, 38 and 40 are withdrawn.

Claims 27-30, 35-37, 39, 41-44, 48-50 and 52 stand rejected.

Applicants note that since the claims have not been amended by this response, the response should not present any new issues for consideration and/or search as they incorporate subject matter already considered by the Office. Accordingly, if the next Office Action on the merits includes a new rejection of one or more claims, the Action must be non-final.

Applicants thank the Examiner for the careful examination of this case and respectfully request reexamination and reconsideration of the case, as amended. Below Applicants address the rejections in the Office Action and explains why the rejections are not applicable to the pending claims as amended.

II. OBVIOUSNESS REJECTIONS

Claims 27-30, 35-37, 39, 42-44, 48-49 and 52 were newly rejected under 35 U.S.C. § 103(a) as allegedly obvious over FARKAS (US 3,360,511) and VITTORI (US 6,482,942) for the reasons on pages 3-4 of the Office Action.

Claims 27-30, 35-37, 39, 42-44, 48-49 and 52 were newly rejected under 35 U.S.C. § 103(a) as allegedly obvious over SHUPE (US 6,290,964) and VITTORI for the reasons on pages 4-5 of the Action.

Claims 27-30, 35-37, 41-44, 48-50 and 52 were newly rejected under 35 U.S.C. § 103(a) as allegedly obvious over JIA (US 2002/0071868A1) and VITTORI for the reasons on pages 5-6 of the Action.

These rejections are respectfully traversed and will be discussed together below. It is noted that the VITTORI patent (US 6,482,942) is newly cited in each rejection.

It is well established that to support a *prima facie* case of obviousness, the Office must provide a rationale showing that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions to yield predictable results. See, *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 U.S.P.Q.2d 1385, 1395 (2007); and M.P.E.P., Eighth Ed., Rev. 6 (September 2007) at § 2143.02.

In the instant case, the claims are concerned with a very unique composition with curative properties, comprising specific isolated polysaccharides. Specifically, in independent claims 27 and 52, the specific polysaccharides, which are derivable from Aloe vera, comprise a chain of linked monosaccharides with "60-100% being D-mannose, 40-0% being D-glucose and 0-10% being other monosaccharides." The specific polysaccharides are moreover prescribed to be "negatively charged" and to "bind to a positively charged column." The polysaccharides also have an "average molecular weight higher than 50 kD."

Applicants respectfully submit that none of the cited references, either alone or in combination, disclose or suggest such specific polysaccharides. Nor do the references disclose or suggest that such specific polysaccharides are negatively charged or bind to a positively charged column.

To start, it is noted that FARKAS fails to disclose or suggest the specific amounts of the polysaccharides ("60-100% being D-mannose, 40-0% being D-glucose and 0-10% being other monosaccharides") in the composition of claims 27 and 52. FARKAS is also silent about polysaccharides that are negatively charged or bind to a positively charged column.

Instead, FARKAS is concerned with polysaccharides comprising about equal parts (35-40%) of glucose and mannose.

Hence, FARKAS does not disclose or suggest polysaccharides comprising at least 60% mannose.

In fact, it could be said that such disclosure in FARKAS actually teaches away from polysaccharides comprising at least 60% mannose. In this regard, it is well established that references cannot be combined where the reference teaches away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). M.P.E.P., Eighth Ed., Rev. 6 (September 2007) at § 2145, X, D, I-III.

In addition, on page 3 of the Office Action, it is noted that the Examiner even acknowledges that FARKAS does not disclose the specific amounts of mannose, glucose and other monosaccharides as claimed. Despite such, at the bottom of page 3 of the Action, the Examiner argues that:

"the extraction of aloe itself is intrinsic to contain the claimed amounts because both the reference and the claimed invention are using the same source for extracting the claimed amounts. Thus, on the extraction of aloe the range of amounts of mannose, glucose and monosaccharides would have to be present in the extract as claimed."

Accordingly, it appears that the Office is applying an inherency argument to an obviousness rejection. However, it should be noted that this is not a 102 anticipation rejection, nor a combination 102/103 anticipation/obviousness rejection. Accordingly, inherency should not be applied.

Moreover, even if inherency were applied, Applicants respectfully disagree and submit that an extract of aloe would

not necessarily intrinsically contain the specific amounts of polysaccharides as claimed. In this regard, FARKAS fails to disclose or suggest the specific amounts of the polysaccharides as claimed.

In addition, there is no indication that FARKAS obtains the same fraction as that recited in the claims as various extraction procedures and protocols would presumably result in different extractions. This is true even if combined with the process in VITTORI. In this regard, VITTORI also fails to disclose or suggest the specific amounts of the polysaccharides as claimed.

Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted). Also, "[a]n invitation to investigate is not an inherent disclosure" where a prior art reference "discloses no more than a broad genus of potential applications of its discoveries." *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367, 71 USPQ2d 1081, 1091 (Fed. Cir. 2004) (explaining that "[a] prior art reference that discloses a genus still does not inherently disclose all species within that broad category" but must be examined to see if a disclosure of the claimed species has been made or whether the prior art reference merely invites further experimentation to find the

species). See also M.P.E.P., Eighth Ed., Rev. 6 (September 2007) at § 2112, IV.

Accordingly, the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). See also M.P.E.P., Eighth Ed., Rev. 6 (September 2007) at § 2112, IV.

Since both references fail to disclose or suggest the specific amounts, and perhaps teach away from such, it cannot be said that FARKAS, even if combined with VITTORI, would necessarily naturally or intrinsically (*i.e.*, inherently) reach the specific amounts of polysaccharides of the claimed composition.

This is true even if FARKAS is combined with VITTORI. The Office relied on VITTORI as disclosing a process to obtain extracts from aloe.

VITTORI is concerned with a method of isolating mucilaginous polysaccharides derivable from Aloe vera. VITTORI does not disclose nor suggest the specific polysaccharides according to the present invention which are negatively charged and bind to a positively charged column.

Moreover, there is no indication or incentive given by VITTORI to isolate specifically negatively charged

polysaccharides using a positively charged column. VITTORI isolates polysaccharides in general by complexation with a tannin. An anion exchange resin is merely applied as wash solution to remove the tannin from a thus formed complex of the polysaccharide. Hence, FARKAS in view of VITTORI does not teach an artisan of ordinary skill to isolate specific polysaccharides that are negatively charged and bind to a positively charged column. Thus, the combination of FARKAS and VITTORI would not necessarily naturally or intrinsically (*i.e.*, inherently) reach the specific amounts of polysaccharides of the claimed composition.

Further, it is well established that a particular parameter or variable must first be recognized as a result-effective variable, *i.e.*, a variable which achieves a recognized result, before the determination of the parameter or variable might be characterized as routine or obvious. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). See also *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). However, no such suggestion is provided by either FARKAS or VITTORI.

Thus, Applicants respectfully disagree with the Office's position that a person of ordinary skill in the art would reach the composition according to the invention merely because FARKAS discloses an Aloe vera extract and VITTORI discloses a process for extraction by routine optimization.

Accordingly, independent claim 27 is believed to be novel and non-obvious over FARKAS in view of VITTORI. The subsequent claims, being dependent on claim 27, are, as a consequence, also deemed to be both novel and non-obvious over the cited prior art.

Thus, the obviousness rejection of FARKAS in view of VITTORI is untenable and should be withdrawn.

As to the other obviousness rejections of SHUPE over VITTORI and JIA over VITTORI, it is noted that the other cited references, SHUPE and JIA, also fail to disclose or suggest the composition of the invention, either taken alone or in any combination. Indeed, in this regard, none of the other references that have been cited disclose or suggest the claimed polysaccharides.

JIA relates to a vehicle for the delivery of biologically active agents. The vehicle, Maxcell, is formulated from a combination of natural plant extracts and is comprised of Aloe vera polysaccharide fraction Immuno-10 (i.e. a very particular type of fraction), cAMP, piperine, calcium phosphate and glycyrrhizinic acid.

SHUPE discloses antimicrobial agents and method for isolation of these agents from a gel liquid of Aloe vera, including at least one antimicrobial agent from the clear gel isolated from the whole leaf of the Aloe vera plant, wherein the

antimicrobial agent is an agent produced by the Aloe vera and/or indigenous bacteria that colonize the Aloe vera plant, is disclosed. Thus, it is not even clear that components from the Aloe plant itself are required.

Moreover, none of them discloses polysaccharides with an amount of D-mannose of at least 60% and an amount of D-glucose of at most 40% that are negatively charged and bind to a positively charged column.

Thus, none of the cited documents, either taken alone or in combination, suggest to one skilled in the art to isolate specifically the negatively charged polysaccharides which are derivable from Aloe vera, that bind to a positive column and have a molecular weight of at least 50 kD, and wherein the polysaccharides comprise 60-100% D-mannose, 0-40% D-glucose and 0-10% other monosaccharides.

The subsequent claims, being dependent on claim 27, are, as a consequence, also deemed to be both novel and non-obvious over the cited prior art.

Thus, the obviousness rejections of SHUPE over VITTORI and JIA over VITTORI are untenable and should be withdrawn.

III. CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is

hereby requested. If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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